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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
YOUNG, MICAH PAUL	

ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
10/18/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/569,160	ASMUSSEN ET AL.	
	Examiner	Art Unit	
	MICAH-PAUL YOUNG	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *14 July 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1,2,7-12,14-24 and 27-41* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1,2,7-12,14-24 and 27-41* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment of Papers Received: Amendment/Response dated 7/18/11.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 2, 7-12, 14-24, and 27-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Fuisz (USPN 4,855,326 hereafter '326) in view of Gillis et al (USPN 6,099,863 hereafter '863) and Uekama et al (USPN 5,904,929 hereafter '929).

The '326 patent discloses a rapidly dissoluble medicinal dosage form in the form of a sheet or wafer (abstract, col. 5, lin. 65-col. 6, lin. 8). The sheet or wafer comprises multiple layers including a foil backing layer (col. 6, lin. 65-col. 7, lin. 7). The dosage form comprises a layer comprising a polymer matrix that serves as an active agent reservoir (col. 7, lin. 10-20). The active substance layer comprises a compound that slows or retards the dissolution of the active agent in the mouth (col. 9, lin. 50-59). The sheet dissolves quickly into a solution without

adhering to the oral tissues and is useful for buccal administration (col. 10, lin. 55-62). The sheet dosage form can comprises approximately 2.5% active agent (col. 8, lin. 15). The sheet comprises flavorings and sweetening agents (col. 7, lin. 20-25). Depending on the active agent the carrier material (sugar or cellulosic material) can comprises from approximately 7-75% (Table IV).

The reference differs from the instant claims in that although anti-Parkinson's drugs are suggested they are not exemplified or specified in the reference. However, the inclusion of specific Parkinson's drugs into quickly dissolving matrices is well known in the art as seen in the '863 patent.

The '863 patent discloses a fast dissolving galanthamine formulation (abstract). The formulation comprises a carrier matrix where the active agent is present in an amount from 2 to 10%, with the support matrix up to 93% (col. 3, lin. 50-65). The support matrix includes a polymeric disintegrants as well as microcrystalline cellulose (***Ibid.***). The formulation comprises other excipients lubricants and fillers (Examples). The formulations dissolve in the oral cavity and begin to deliver their active payloads within 5 minutes (Example 6). The formulation can be used to treat chemical dependency such as nicotine dependency and cravings, Alzheimer's Dementia and associated symptoms and side effects, including impaired memory, negative sides effects of psychotropic treatments such as benzodiazepine and general mania, chronic fatigue syndrome (col. 1, lin. 43-65).

It would have been obvious to include the galanthamine salt of the '863 patent into the thin oral sheets of '326 patent since the '326 reference is suggestive of cholinesterase inhibitors and discloses fast dissolving oral dosage forms. The combination would have been obvious

following the suggestions of the '326 application and teachings of the '863 to quickly deliver the compounds orally. The combination would have been obvious to one of ordinary skill in the art in order delivery a quick relief to those suffering from chemical dependency.

Regarding the dissolution profile recited in the claims 30 and 31, it is the position of the Examiner that such limitations would be inherently met by the prior art. The claims recite a film comprising a galanthamine compound and a polymer dissolves within a specified time and achieves a specific plasma level. However the dissolution rate is a functional limitation that does not define a structure. The functional limitation is solely dependent on the compositional components of the claim, and as such since the only compositional components of the claim are a thin film comprising a galanthamine compound and a polymer, the compositional components art met. Since the same compounds must have the same features and function, the thin film of the prior art combination that comprises a galanthamine compound and a polymer inherently will dissolve within 30 minutes and achieved an optimal plasma concentration. "Products of identical chemical composition cannot have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

The combination while discloses galanthamine derivatives in a film form is silent to multiple compounds in the strip. This however would be an obvious addition to the film in order to increase the effectiveness of the dosage form. It would be obvious to add additional similarly acting compounds to the formulation in order to increase the effectiveness of the dosage form. These other compounds are well known in the art as seen in the '929 patent.

The '929 patent discloses oral formulations comprising a range of active agents including parasympathomimetics such as galanthamine, neostigmine and tacrine (col. 6, lin. 20-23). The dosage forms include trans-mucosal or transdermal films, or tablets (col. 4, lin. 1-20). The formulation further comprises microcrystalline cellulose, and hydroxypropylcellulose (Example 13). It would have been obvious to add these other cholinesterase inhibiting compounds to the combination of the '326 and '863 films in order to increase the effectiveness. It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. The idea of combining them flows logically from their having been individually taught in the prior art. *See* In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

One of ordinary skill in the art would have been motivated to combine the galanthamine salt of the '863 patent into the film composition of the '326 reference in order to quickly deliver the compounds to patients suffering from chemical dependency. The combination would have been obvious since both references disclose oral delivery of systemic compounds in compositions comprising similar amounts of the active agents and polymer matrix components. Both references also disclose similar carrier matrices comprising flavors, fillers and carriers. Both formulations are designed to dissolve quickly in the mouth. It would have been obvious to combine the further cholinesterase inhibitory compounds of the '929 patent into the combination of the '326 and '863 reference since each patent discloses a similar composition comprising the similar active agents, in similar polymeric matrices that are all delivered orally. This combination would have been obvious in order to increase the effectiveness of the dosage form in treating chemical dependency. One of ordinary skill in the art would have been motivated to

combine the prior art with an expected result of a buccal film useful in the treating chemical dependency.

Response to Arguments

Applicant's arguments filed 7/18/11 have been fully considered but they are not persuasive. Applicant argues that:

The combination of prior art does not obviate the instant claims since the combination comprises "fibrous material" and would be mucoadhesive, thereby not obviating the instant thin film composition.

Regarding this argument it remains the position of the Examiner that the combination of the prior art continues to obviate the instant claims. 326 discloses a thin film that dissolves in saliva very quickly (col. 9, lin. 50-59). Applicant argues that the thin composition comprises "fibrous materials" that would adhere the devices to the mucosa. However the reference is silent to any adhesion. Further the claims do not foreclose the inclusion of other materials, and in fact dependent claim recite the inclusion of sweeteners and fillers (instant claims 12) which can include the same materials as recited by 326. 326 discloses a thin device that delivers an active agent to the mouth and quickly dissolves before adhesion, this meets the general conditions of the instant claims. The reference discloses anti-Parkinson's drugs and it would have been obvious to include specific compound in quick dissolving formulation such as 326. This can be found in 863 where a fast dissolving galanthamine formulation is disclosed (abstract). The formulation delivers its payload within 5 minutes and comprises similar excipients as 326. 929 discloses the addition of further active components. It would have been obvious to include these compounds in order to improve the activity of the thin film compounds of the combination.

There would have been a reasonable level of success since the additional active agents are present in similar thin film product comprising similar disintegrants and supporting polymers. This combination would have been obvious in order to increase the effectiveness of the dosage form in treating chemical dependency. One of ordinary skill in the art would have been motivated to combine the prior art with an expected result of a buccal films that dissolve quickly and have been useful in the treating chemical dependency. For these reasons the claims remain obviated.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICAH-PAUL YOUNG whose telephone number is (571)272-0608. The examiner can normally be reached on Monday-Thursday 7:00-5:30; every Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/MICAH-PAUL YOUNG/
Examiner, Art Unit 1618

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618